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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/563,633

01/06/2006

Masao Ieno

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WASHINGTON, DC 20006-1021

EXAMINER

SIMMONS WILLIS, TRACEY A

ART UNIT

PAPER NUMBER

1619

MAIL DATE

DELIVERY MODE

12/31/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/563,633	<b>Applicant(s)</b> IENO ET AL.	
	<b>Examiner</b> TRACEY SIMMONS WILLIS	<b>Art Unit</b> 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 15-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01062006; 01312007</u> .                                      | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of the Claims***

Applicant's election **without** traverse in the reply filed on November 3, 2008 is acknowledged.

Claims 15-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention there being no allowable generic or linking claim.

Examination will commence on this time on claims 1-14 only. This is the first Office Action on the merits of the claims.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regards to claims 1-14, the term "amino acid derivative" is used and the definition given in the Specification includes "part of functional groups in amino acid molecule" (p 13). Examiner asserts that one of ordinary skill in the art would not be able to easily ascertain what part of the functional groups in the molecule would infringe on the claim. Clarification is required.

Because claims 2-14 depend from indefinite claim 1 and do not clarify the point of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

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Claim 2 cites the term “eluting rate”, and the definition given in the (p 10) relates the elution rate values ( $\alpha$  and  $\beta$ ) to be associated with a skincare feel, however no referral to skin is given in the claim. Examiner asserts that one of ordinary skill in the art would not be able to easily ascertain an elution rate as no referral to skin is mentioned within the claim therefore the meets and bounds of the claim are not defined. Clarification is required.

Claim 3 cites the term “impregnated therein” which is rendered indefinite as Examiner is unclear of what it is the solution is impregnated therein. Clarification is required.

Furthermore, within claim 3, the phrase “after release” is rendered indefinite as the term implies a reference as related to time, however the claim is directed toward a product and not a method, therefore a referral to a time frame is inappropriate. Clarification is required.

Claim 4 includes two periods and Examiner is uncertain of where the claim ends as periods are only used at the end of a claim (see MPEP 608.01(m)). Clarification is required.

Claim 5 cites the term “basic amino acid” which Examiner can interpret to mean either an amino acid with basic functional groups or an essential amino acid. Clarification is required.

Claim 7 includes an abbreviation “RH”, which has not been previously defined within the claims. Clarification is required.

Claim 9 cites the term “amino acid type” which is not defined within the claim or Specification. Examiner finds one of ordinary skill in the art would not be able to ascertain if acrylic acid type includes polymers that necessarily contain acrylic acid or acrylate, or a polymer that functions like acrylic acid. Clarification is required.

Claim 10 is incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See

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MPEP § 2172.01. The omitted structural cooperative relationships are: how is the cross-linked structure defined? Is the polymer self-crosslinking or is the polymer cross-linked to another polymer? Clarification is required.

Claim 11 cites the term “hydrazine type” which is not defined within the claim or Specification. Examiner finds one of ordinary skill in the art would not be able to ascertain if “hydrazine type” includes polymers that necessarily contain hydrazine or a polymer that functions like hydrazine, e.g. Clarification is required.

Claim 12 cites the term “formed by copolymerization” which is not defined, as Examiner finds one of ordinary skill in the art would not be able to ascertain what the monomer is copolymerized with. The prefix “co-“ implies a second component that is not named or characterized. Clarification is required.

Claim 13 cites the term “particles” which is not defined, and Examiner finds one of ordinary skill in the art would not be able to ascertain if the polymer is contained within particles of something else or if the polymer itself is a particle. Clarification is required.

Claim 14 cites the term “fibrous” which is not defined, and Examiner finds one of ordinary skill in the art can interpret to mean an agglomerate of fibers or a long, linear polymer. Clarification is required.

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-14 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,807,364 (Hansen).

Hansen teaches of fibrous webs that use binders to bind particulates to fibers. Binders include amino acids [col 5, line 65], such as lysine [col 15, line 23] and suitable fibers include self-crosslinking acrylic acid [col 13, lines 61-62] and modified crosslinked polyvinyl alcohol [col 13, lines 60-61]. The amino acid forms an ionic bond with anionic groups on the fibers or particles [col 6, lines 4-6]. With regard to claim 5, Examiner interprets "basic amino acid" to be an amino acid with a basic functional group. With regard to claims 13 and 14, Examiner interprets "in particles" to be within particles, and "is fibrous" to be an agglomerate of fibers. The limitations cited in claims 2, 3, and 7 are rendered inherent properties of the product, absent evidence to the contrary. Examiner asserts that the structure of the sustained release polymer is taught and hence the properties of the polymer cannot be separated from the polymer itself (see MPEP 2112.01). Claims 11 and 12 are product-by-process claims which do not provide additional limitations to claim 10. As stated in MPEP 2113, product-by-process claims are not limited to the recited steps, only the structure implied by the steps.

***Conclusion***

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to TRACEY SIMMONS WILLIS whose telephone number is (571)270-5861. The examiner can normally be reached on Mondays to Fridays from 8:30 am to 5:30 pm. The examiner can also be reached on alternate Fridays from 8:30 am to 12:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/T. S.W./

Examiner, Art Unit 1619

/Lora E Barnhart/

Primary Examiner, Art Unit 1651